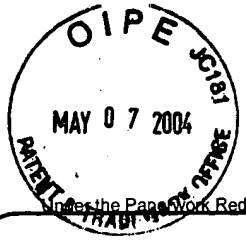
120




AF/3761 IFW

PTO/SB/21 (08-03)
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# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| | |
|---|---|
| Application Number | 09/818,228 |
| Filing Date | March 27, 2001 |
| First Named Inventor | Kent L. Christopher |
| Art Unit | 3761 |
| Examiner Name | M. Patel |
| Total Number of Pages in This Submission: 20 | Attorney Docket Number: 1246/39(a) |

## ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
- [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance communication to Technology Center (TC)
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please Identify below):

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | |
|---|---|
| Firm or Individual name | Thomas S. Birney, Esq.<br>Dorr, Carson, Sloan, Birney & Kramer, P.C. |
| Signature | Thomas S Birney |
| Date | May 7, 2004 |

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| Signature | Thomas S Birney | Date | May 7, 2004 |

PTO/SB/17 (10-03)
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# FEE TRANSMITTAL for FY 2004

*Effective 10/01/2003. Patent fees are subject to annual revision.*

☑ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) 165

| *Complete if Known* | |
|---|---|
| Application Number | 09/818,228 |
| Filing Date | March 27, 2001 |
| First Named Inventor | Kent L. Christopher |
| Examiner Name | M. Patel |
| Art Unit | 3761 |
| Attorney Docket No. | 1246/39(a) |

## METHOD OF PAYMENT *(check all that apply)*

☑ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 04-1414

Deposit Account Name: Dorr, Carson, Sloan & Birney, P.C.

**The Director is authorized to:** *(check all that apply)*

☐ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |

**SUBTOTAL (1)** ($)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | Extra Claims | | Fee from below | Fee Paid |
|---|---|---|---|---|---|
| Total Claims | | -20** = | | X | = |
| Independent Claims | | - 3** = | | X | = |
| Multiple Dependent | | | | | = |

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

**SUBTOTAL (2)** ($)

**or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for *ex parte* reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | 165 |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3)** ($) 165

## SUBMITTED BY

(Complete *(if applicable)*)

| Name *(Print/Type)* | Thomas S. Birney | Registration No. *(Attorney/Agent)* | 30,025 | Telephone | (303) 333-3010 |
|---|---|---|---|---|---|
| Signature | Thomas S Birney | | | Date | May 7, 2004 |

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

| | |
|---|---|
| In re Application of<br>Kent L. Christopher | |
| Serial No. 09/818,228 | Examiner M. Patel<br>Group Art Unit 3761 |
| Filed: March 27, 2001 | |
| For: METHOD AND APPARATUS FOR PHARYNGEAL AUGMENTATION OF VENTILATION | |

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, under 37 CFR 1.10 on the date indicated below addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Thomas S Birney
Signature

May 7, 2004
Date Deposited

Thomas S. Birney - 30,025

ER 824854840 US
"Express Mail" Label Number

## BRIEF FOR APPELLANT

### *Real Party in Interest*

CS Medical, Inc., a Colorado corporation having a place of business at 6151 Songbird Circle, Boulder, Colorado 80303, is the owner of record of the application by virtue of the assignment recorded at Reel 014079, Frame 0461 on May 19, 2003, and is the real party of interest.

***Related Appeals and Interferences.***

The Appellant does not know of any other appeals or interferences that would directly affect or be directly affected by or have any bearing on the Board's decision in the pending appeal.

***Status of Claims.***

The application with claims 1 through 28 (including independent claims 1, 15, and 23) was filed on March 27, 2001.

In the first Office Action, mailed October 5, 2001, claims 1 - 28 were rejected. Specifically, claims 1 - 22 were rejected under 35 U.S.C. §101 for being directed to non-statutory subject matter because the claims positively recited a part of the human body. Claims 1 - 4, 8, 11 - 17, 19, 20, 23 - 25 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke (U.S. Patent No. 3,915,173). (Paragraphs 2 and 17 of this Office Action apparently contain several typographical errors regarding the claim numbers in this rejection. However, the claims listed above appear to be correct based on the text and substance of the rejection.) Claims 5, 6, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al. Claims 7 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al.

In the Amendment filed on November 13, 2001, the Appellant amended claims 1 and 15 to address a rejection under 35 U.S.C. §101. The Appellant respectfully traversed the obviousness rejections of claims 1 - 28 and presented arguments in support thereof.

In the second Office Action, mailed January 31, 2002, the previous obviousness rejections of claims 1 - 28 were made final.

In the Amendment filed on March 19, 2002, the Appellant respectfully traversed the obviousness rejections of claims 1 - 28 and presented arguments in support thereof.

The Amendment also amended claims 1, 15 and 23 to clarify that the present invention is an "open" system that does not obstruct the patient's spontaneous breathing, unlike the endotracheal tube disclosed by Brekke. An Advisory Action was mailed on April 11, 2002, refusing to enter this Amendment.

A Request for Continued Examination (RCE) was filed on April 17, 2002, along with a copy of the Amendment previous filed on March 19, 2002.

The third Office Action, mailed on May 2, 2002, continued the obviousness rejections of claims 1 - 28.

In the Amendment filed on July 23, 2002, claims 1, 15 and 23 were amended once again to further clarify that the present invention is an "open" system to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, unlike Brekke.

A fourth, final Office Action, mailed on September 23, 2002, continued the obviousness rejections of claims 1 - 28.

A Request for Reconsideration was filed on December 18, 2002, discussing the differences in the structure between the present invention and Brekke, and also discussing the pathophysiology of respiratory failure, respiratory insufficiency, and sleep apnea. An Advisory Office Action was mailed on January 23, 2003.

A Notice of Appeal was filed on February 7, 2003, and an Appeal Brief was filed on April 4, 2003.

A fifth Office Action, mailed on June 18, 2003, reopened prosecution and raised new grounds for rejecting all of the claims. In particular, claims 1, 2, 6, 8, 11 - 15, 20, 23, 25 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi (U.S. Patent No. 6,394,093). Claims 3 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Bowden et al. (U.S. Patent No. 6,374,827). Claims 4 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Brain (U.S. Patent No. 6,055,984). Claims 5 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Dali et al. (U.S. Patent No.

3,682,171). Claims 7 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Spofford et al. (U.S. Patent No. 5,297,546). Claims 9, 10, 21, 22, 26, and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Daniell et al. (U.S. Patent No. 6,050,260). Claim 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Linder et al. (U.S. Patent No. 3,957,055).

In the Amendment filed on September 17, 2003, Applicant respectfully traversed these rejections and presented arguments in support thereof. Claims 1, 15 and 23 were amended once again to distinguish Lethi. Minor amendments were also made to claims 8, 11 and 20.

A sixth, final Office Action, mailed on November 19, 2002, continued the obviousness rejections of claims 1 - 28 and also objected to some of the amendments to claims 1, 15 and 23 as introducing new matter.

In the Amendment After Final Rejection filed on February 10, 2004, claims 1, 15 and 23 were amended to cancel the new matter objected to in the final Office Action. An Advisory Office Action was mailed on February 25, 2004, entering these amendments.

A second Notice of Appeal was filed on March 9, 2004, along with a petition for a one-month extension of time. This is an appeal from the final rejection of claims 1 - 28 by the final Office Action, dated November 19, 2003. Claims 1 - 28 are the subject of this appeal and are attached hereto, as finally rejected, in the Appendix.

***Status of Amendments.***

The Amendment After Final Rejection filed on February 10, 2004, has been entered.

***Summary of the Invention.***

This invention is a nasopharyngeal catheter for direct pharyngeal delivery of high flows of humidified air, oxygen, helium, or other gases to supplement ventilation of a spontaneously breathing patient. Flow rates in the range of approximately 4 to 40 liters per minute can be employed. In one embodiment, the flow passes through a heater that maintains a desired temperature, and a humidifier that maintains a desired relative humidity. The present invention may also include a nasal catheter that can be cut to a desired length and removably attached to a horizontal delivery tube. Gas can be supplied through oxygen connections at either end of the horizontal delivery tube.

For example, the present invention can be used for the purpose of treating patients with respiratory failure or insufficiency, or sleep apnea syndrome. In a home setting, the present invention can be employed to augment nocturnal ventilation of patients with sleep apnea syndrome (obstructive, central, or mixed), or chronic respiratory failure or insufficiency resulting from emphysema (COPD), other obstructive lung diseases, interstitial lung diseases, pleural diseases, neuromuscular diseases, and other restrictive disorders. In a hospital setting, the present invention can be used to treat patients with acute respiratory failure/insufficiency or acute respiratory failure/insufficiency superimposed upon chronic respiratory failure/insufficiency. The present system can be used intermittently or throughout the day and night to augment ventilation and avoid the need for endotracheal intubation and conventional mechanical ventilation.

The present invention offers a number of advantages over the prior art in treatment of sleep apnea and respiratory failure/insufficiency. No surgical procedure is required. The device is more comfortable and less obtrusive for the patient to wear. The catheter effectively bypasses any obstructions in the patient's nasal cavity and nasopharynx. The high flow of gas can also helps to relieve any obstruction between the nasopharynx and trachea (e.g., obstruction by the tongue). The flow of air/oxygen is thoroughly humidified, which reduces accumulation of mucus and drying of the patient's

airway. There are no constraints on the patient during periods when the patient is not receiving therapy. In addition, the present system can be used to deliver a variety of gases including air (for sleep apnea and neuromuscular disorders), air and oxygen (for hypoxemia), and helium and oxygen (for enhanced gas transport and other physiologic benefits, such as reduced work of breathing).

***Issues.***

The following issues are on appeal:

1. Whether claims 1, 2, 6, 8, 11 - 15, 20, 23, 25, and 28 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi?

2. Whether claims 3 and 16 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Bowden et al.?

3. Whether claims 4 and 17 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Brain?

4. Whether claims 5 and 18 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Dali et al.?

5. Whether claims 7 and 19 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Spofford et al.?

6. Whether claims 9, 10, 21, 22, 26, and 27 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Daniell et al.?

7. Whether claim 24 was improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Linder et al.?

***Grouping of Claims.***

Claims 1, 2, 6, 8, 11 - 15, 20, 23, 25, and 28 stand or fall together. The patentability of these apparatus claims turns on whether each is obvious over Lethi.

Claims 3 and 6 include limitations relating to markings on the nasal catheter to indicate a series of common lengths, and therefore stand or fall together. The patentability of these claims turns on whether each is obvious over Lethi in view of Bowden et al.

Claims 4 and 17 include limitations relating to a radio-opaque stripe on the nasal catheter, and therefore stand or fall together. The patentability of these claims turns on whether each is obvious over Lethi in view of Brain.

Claims 5 and 18 include limitations relating to connectors for the device, and therefore stand or fall together. The patentability of these claims turns on whether each is obvious over Lethi in view of Dali et al.

Claims 7 and 19 include the limitation of a hydrophilic coating, and therefore stand or fall together. The patentability of these claims turns on whether each is obvious over Lethi in view of Spofford et al.

Claims 9, 10, 21, 22, 26, and 27 include limitations requiring regulation of the temperature or humidity of the gas delivered through the nasal catheter, and therefore stand or fall together. The patentability of these claims turns on whether each is obvious over Lethi in view of Daniell et al.

Claim 24 is a method claim that includes an element relating to cutting the proximal end of the catheter so that the distal tip of the catheter will have a desired position relative to the patient's uvula. The patentability of this claim turns on whether it is obvious over Lethi in view of Linder et al.

***Argument***

**Issue 1**

Claims 1, 2, 6, 8, 11 - 15, 20, 23, 25, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi. Applicant notes that all of the independent claims (i.e., claims 1, 15 and 23) specify that the nasal catheter in the present invention does not restrict the patient's spontaneous respiration through the nasopharynx, unlike Lethi.

Lethi's tube 1 includes an inflatable cuff 3 that creates an air-tight obstruction between the nasopharynx and the rest of the patient's breathing passage. The cuff 3 is intended to block unwanted secretions from the nasal area from draining into the throat and lungs (col. 5, lines 23 - 26). However, the cuff 3 also blocks nasal respiration, except through the tube 1. With unrestricted spontaneous breathing, the nasopharynx serves to heat, humidify and filter air. These natural functions are prevented with the Lethi invention. Lethi's device is similar to other conventional artificial airways (e.g., nasopharyngeal airways, nasotracheal and oral endotracheal tubes) in that resistance to air flow (and restriction of spontaneous breathing) can be high and the work of breathing through the passageway of the airway is significantly increased. The single most important factor affecting ventilatory muscle function and work of breathing is the artificial airway, even if the patient is on ventilatory assistance. The increase in resistance and restriction to breathing through an artificial airway can be most devastating with pre-existing ventilatory muscle dysfunction (i.e., patients with respiratory failure or insufficiency), but resistance and restriction may also precipitate fatigue in previously healthy individuals if the patient's ventilation requirements are high.

The central passage in Lethi's tube is also intended to allow introduction of feeding tubes, suction catheters and observation probes. Lethi calls for having the cuff inflated during these procedures to prevent inadvertent dislodgement of the airway

when such devices are removed. Placement of these devices in the breathing passage further increases resistance and restriction to breathing through the tube, and the inflated cuff prohibits any nasal breathing around the airway.

The Lethi device is intended for short-term use in surgery or post-op recovery or "waking up" period and is also advocated for use in emergency and critical care. Nasopharyngeal airways such as the Lethi device are indicated for maintaining a breathing passage in patients who can not maintain an airway due to an altered level of consciousness due to anesthesia or acute illness. These individuals can tolerate a large airway in the nasopharynx and back of their throat. However, truly conscious patients will not likely tolerate the large airway and inflated cuff pushing against the soft palate and throat, because they will produce a gag reflex, aerophagia, or air swallowing and interfere with, or restrict eating and drinking. In contrast, the present small nasopharyngeal catheter can be inserted nightly before bed by patients with sleep apnea and chronic respiratory failure and insufficiency. Patients with acute respiratory failure or insufficiency can use it continuously for days and the functions of eating and drinking will not be restricted.

In addition, nothing in Lethi teaches or suggests a gas source with a flow rate of 4 - 40 liters per minute, as required in each of the independent claims. The primary lumen of the tube 1 is apparently intended only as a conduit for the patient's spontaneous respiration. Lethi discloses a second, oxygen supply lumen 5 or 5b built into the wall of the tube 1, which is suitable only for delivering low flow rates of oxygen. The typical flow rate of 1 to 2 L/min may be generally adequate to correct blood oxygen levels. In contrast, the present invention delivers a high flow rate of air (or air enriched with oxygen) that goes beyond the goal of improving blood oxygen levels to reduced the patient's work of breathing, improve alveolar ventilation, or wash out of carbon dioxide from the patient's airway. However, nothing in Lethi teaches or suggests the claimed range of flow rates. Delivering excessive pure oxygen at such flow rates would tend to suppress the patient's respiration through ablation of the hypoxic respiratory drive, and may result in a type of

respiratory failure called $CO_2$ narcosis, which is a potentially fatal condition for the patient. Similarly, excessive oxygen administration may cause a condition called oxygen toxicity.

Regarding claims 2 and 15, nothing in Lethi teaches or suggest a catheter that can be trimmed to a desired length. The airway disclosed by Lethi has a fixed length. The cuff at the distal end of the tube and the conduits at the upper end of the Lethi device would make it impossible to trim such a device while maintaining its intended functionality.

With regard to claim 25, nothing in Lethi teaches or suggests cutting the tube so its distal tip will have a desired position relative to the patient's uvula. As previously noted, cutting the distal end of the Lethi device would destroy its functionality.

As to claims 14 and 28, nothing in Lethi teaches or suggest the use of helium. The low density and viscosity of helium significantly reduce the patient's work of breathing.

**Issue 2**

Claims 3 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Bowden et al. In response, Applicant notes nothing in Lethi or Bowden et al. teaches or suggests a plurality of markings for cutting a nasal catheter to a desired length. Trimming the length of the devices disclosed by Lethi or Bowden et al. would destroy their functionality. The integrity of the inflatable cuff 3 would be lost if the distal end of the Lethi device is trimmed. The connectors, cuff inflation lumen, and safety flange 2 would be lost if the proximal end of the Lethi device is trimmed. Similarly, the device disclosed by Bowden et al. has an inflatable cuffs at its distal ends and connectors at its proximal ends.

In addition, Applicant notes that both of these are dependent claims. Applicant submits that the invention defined in each of these dependent claims should be considered as a whole, and restates the previous comments concerning Lethi regarding independent claims 1, 15 and 23. The specific elements provided by these dependent

claims should be considered in combination with the elements of their respective independent claims, rather than as isolated elements by themselves.

**Issue 3**

Claims 4 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Brain. These dependent claims require a radio-opaque stripe on the nasal catheter. Brain discloses an endotracheal tube with an radio-opaque. However, nothing in Lethi or Brain teaches or suggests the desirability of combining Lethi and Brain. Applicant also notes that these are dependent claims and restates the previous comments concerning Lethi as applied to independent claims 1, 15 and 23.

**Issue 4**

Claims 5 and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Dali et al. These dependent claims require a delivery tube with two opposing end connectors and a cap that is removably insertable into the unattached end connector. Dali et al. have been cited as showing a removable cap. In response, Applicant submits that Lethi's extension tube 9 is not a delivery tube as required in these claims because it does not have two opposing ends with connectors for attachment to the gas source.

**Issue 5**

Claims 7 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Spofford et al. These dependent claims require a hydrophilic coating on the nasal catheter. Spofford et al. discloses a transtracheal catheter with a hydrophilic coating. However, nothing in Lethi or Spofford et al. teaches or suggests

the desirability of combining these references. Applicant also notes that these are dependent claims and restates the previous comments concerning Lethi as applied to independent claims 1, 15 and 23.

**Issue 6**

Claims 9, 10, 21, 22, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Daniell et al. These dependent claims include limitations requiring regulation of the temperature or humidity of the gas delivered through the nasal catheter. Daniell et al. disclose an apparatus for supplying humidified, heated gases via a face mask for treatment of sleep apnea. In response, Appellant restates the previous comments concerning Lethi, and submits that the invention defined in each of these dependent claims should be considered as a whole. The specific elements provided by each of these dependent claims should be considered in combination with the elements of their respective independent claims, rather than as isolated elements by themselves.

**Issue 7**

Claim 24 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Lethi in view of Linder et al. This dependent method claim that includes the step of cutting the proximal end of the catheter so that the distal tip of the nasal catheter will have a desired position relative to the patient's uvula. Linder et al. discloses a catheter guide or stylet. Linder et al. mention that "disposable endotracheal tubes" can be "cut to approximate length prior to insertion of the guide" (column 2, lines 44 -45). However, nothing in Linder et al. teaches or suggests the steps of advancing a nasal catheter through the patient's nostril until its distal tip is visible through the patient's mouth below the uvula, and then cutting the proximal end of the catheter to a desired length, as set forth

in claim 24. Applicant also notes that this is a dependent claim and restates the previous comments concerning Lethi as applied to independent claim 23.

***Summary***

For the foregoing reasons, the Appellant believes that the rejections of claims 1 - 28, as set forth in the final Office Action, were erroneous. Therefore, Appellant respectfully urges the Board to allow claims 1 - 28.

A check is enclosed in the amount of $165.00 pursuant to 37 C.F.R. §1.17(c) for filing a brief in support of an appeal for a small entity. If any fees in addition to those already paid are required, please debit Deposit Account 04-1414.

Respectfully submitted,

DORR, CARSON, SLOAN, BIRNEY & KRAMER, P.C.

Date: 5/7/04

By: Thomas S Birney

Thomas S. Birney #30,025
3010 East 6th Avenue
Denver, Colorado 80206
(303) 333-3010

Attorneys for Appellant

## APPENDIX

1. A nasopharyngeal catheter for open delivery of a continuous flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without restricting the patient's spontaneous respiration through the patient's nasopharynx or oropharynx;

a delivery tube adapted to extend below the patient's nostril connected to the proximal end of the nasal catheter; and

a gas source delivering a continuous flow of air/oxygen at a rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx to supplement the patient's respiration.

2. The nasopharyngeal catheter of claim 1 wherein the nasal catheter comprises a flexible plastic tube that can be cut to a desired length.

3. The nasopharyngeal catheter of claim 2 wherein the nasal catheter further comprises a plurality of markings indicating a series of common lengths for the nasal catheter.

4. The nasopharyngeal catheter of claim 1 wherein the nasal catheter further comprises a radio-opaque stripe.

5. The nasopharyngeal catheter of claim 1 wherein the delivery tube further comprises;

two opposing ends with connectors for removable attachment to the gas source; and

a cap removably insertable into a connector that is not attached to the gas source.

6. The nasopharyngeal catheter of claim 1 further comprising a connector for removably attaching the proximal end of the nasal catheter to the delivery tube.

7. The nasopharyngeal catheter of claim 1 wherein the nasal catheter further comprises a hydrophilic coating.

8. The nasopharyngeal catheter of claim 1 wherein the nasal catheter has an inside diameter of up to approximately 3 mm.

9. The nasopharyngeal catheter of claim 1 further comprising a humidifier controlling the humidity of the gas delivered through the nasal catheter.

10. The nasopharyngeal catheter of claim 1 further comprising a heater controlling the temperature of the gas delivered through the nasal catheter.

11. The nasopharyngeal catheter of claim 1 wherein gas is supplied through the nasal catheter at a back pressure of up to approximately 25 psi.

12. The nasopharyngeal catheter of claim 1 wherein the gas supplied through the nasal catheter comprises oxygen.

13. The nasopharyngeal catheter of claim 1 wherein the gas supplied through the nasal catheter comprises air.

14. The nasopharyngeal catheter of claim 1 wherein the gas supplied through the nasal catheter comprises helium.

15. A nasopharyngeal catheter for open delivery of a continuous flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without restricting the patient's spontaneous respiration through the patient's nasopharynx or oropharynx, said catheter being made of a flexible material that can be trimmed to a desired length;

a delivery tube adapted to extend below the patient's nostril having a connector for removable attachment to the proximal end of the nasal catheter; and

a gas source delivering a continuous flow rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx to supplement the patient's respiration.

16. The nasopharyngeal catheter of claim 15 wherein the nasal catheter further comprises a plurality of markings indicating a series of common lengths for the nasal catheter.

17. The nasopharyngeal catheter of claim 15 wherein the nasal catheter further comprises a radio-opaque stripe.

18. The nasopharyngeal catheter of claim 15 wherein the delivery tube further comprises;

two opposing ends with connectors for removable attachment to the gas source; and

a cap removably insertable into a connector that is not attached to the gas source.

19. The nasopharyngeal catheter of claim 15 wherein the nasal catheter further comprises a hydrophilic coating.

20. The nasopharyngeal catheter of claim 15 wherein the nasal catheter has an inside diameter of up to approximately 3 mm.

21. The nasopharyngeal catheter of claim 15 further comprising a humidifier controlling the humidity of the gas delivered through the nasal catheter.

22. The nasopharyngeal catheter of claim 15 further comprising a heater controlling the temperature of the gas delivered through the nasal catheter.

23. An open delivery method for providing a supplemental continuous flow of air/oxygen to a spontaneously breathing patient in the treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, the method comprising:

advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx without restricting the patient's spontaneous respiration through the patient's nasopharynx or oropharynx; and

supplying air/oxygen through the catheter at a continuous flow rate of approximately 4 to 40 liters per minute into the patient's distal nasopharynx or oropharynx to supplement the patient's respiration.

24. The method of claim 23 further comprising the initial steps of:

providing a delivery tube extending beneath the patient's nostril for delivering the flow of air/oxygen, said delivery tube having a connector for attachment to the catheter;

advancing the catheter through a patient's nostril until the distal tip of the catheter is visible through the patient's mouth below the patient's uvula;

cutting the proximal end of the catheter to a desired length so that the distal tip of the catheter will have a desired position relative to the patient's uvula;

attaching the proximal end of the catheter to the connector on the delivery tube.

25. The method of claim 23 further comprising the initial step of selecting the length of the catheter by advancing a catheter through a patient's nostril until the distal tip of the catheter is visible through the patient's mouth below the patient's uvula.

26. The method of claim 23 further comprising controlling the humidity of the air/oxygen supplied through the catheter.

27. The method of claim 23 further comprising regulating the temperature of the air/oxygen supplied through the catheter.

28. The method of claim 23 further comprising supplying helium through the catheter.